K121435

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Home Skinovations Ltd.
Silkn Blue

FEB 22 2013

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Tavor building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silkn Blue
Common/Usual name:	Acne Treatment device
Classification name:	Over the counter powered light based laser for Acne, 21 CFR 878.4810
Product code:	OLP

Predicate devices

- ThermaClear by DermaCare Inc. K060653.
- Quasar Blue Light Therapy System by Silver Bay LLC, K093963.
- Tanda Skincare System, by Pharos Life Corporation, K080591
- OmniLux New-U, by Photo Therapeutics Inc, K081307.

Intended use:

The Silkn Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne.

Device Description & technology comparison to predicate device:
Silkn Blue is a hand held device battery operated that uses low power light spectrum, LED, at wavelength of 415 ±15 nm, combine with tip temperature stabilizer at 41^0C. The emitting optical power is in a uniform distribution with no hot spots.

Technology comparison of Silkn Blue with predicate devices:

	Silkn Blue	ThermaClear	*Quasar Blue*	*Tanda Skincare*	*OmniLux Clear-U*
Energy Source	LED + Tip temperature stabilizer	Tip temperature stabilizer	LED	LED	Dual wavelengths LED
Wavelengths (nm)	415	NA	415	415	415, 633
Power mW/cm^2	50	NA	50	50	40(415 nm), 70(633 nm)
Treatment area cm^2	7	1	10	27	30
Targeted skin temperature ^0C	41±2	41-43		39-43	39-43
Patient contacting material	Stainless steels 17-4PH, Rigid ABS	Stainless steels	Rigid ABS	Rigid ABS	Rigid ABS

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CFR § 1040.10 & 1040.11

Clinical study summary:

The clinical and usability research study performed to determine the ability of the Silkn Blue device to treat mild to moderate inflammatory acne, and to determine if the average person is able to use the device properly according to the labeling as describe in the operator manual.
The clinical study involves 50 subjects who used the Silk'n Blue twice a week over four weeks (a total of 8 treatments), and 2 follow-up visits to evaluate the results.
All subjects demonstrated a reduction in lesion count.
The average improvement after one month was 56.7%±8.9%, and remained similar also after 3 months 57.7%±9.4%.
The users were asked to fill a questionnaire regarding the device use and labeling.
Safety was evaluated by monitoring immediate reaction and adverse effects. There were no other adverse effects associated with the treatment.

Substantial Equivalence:

The Silkn Blue is substantial equivalent to its predicate device. The data in this 510(k) submission demonstrate that the Silkn Blue device has compatible output as the predicate devices, and identical intended use. Therefore is substantial equivalent to its predicate devices.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the ,Silkn Blue should raise no new issues of safety or effectiveness.

May 10, 2012

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Home Skinovations, Limited
% Dr. Amir Waldman
Vice President, Regulatory Affairs
Tavor Building, POB 533
Yokneam Illit, Israel 20692

Re: K121435
Trade/Device Name: Silkn Blue
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: January 09, 2013
Received: February 13, 2013

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, For:

Peter D. Rumm -S

Mark
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K121435

Device Name Silkn Blue

Indications For Use:

The Silkn Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne.

Prescription Use_____ OR Over The Counter Use X
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.02.21 15:34:39 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K121435